

### **REMARKS/ARGUMENTS**

Claims 11-19 and 21-29 are pending. Claims 11-19 and 21-28 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,931,276 to Streng et al. in view of U.S. Patent No. 5,662,108 to Budd et al. Claim 29 was rejected as being unpatentable over Streng in view of Budd as applied to Claim 11, and further in view of Webster's II New Riverside University Dictionary.

#### **Response to Rejections**

The rejections all hinge upon the Office Action's assertion that a person skilled in the art having to do with bladder diagnosis and treatment (i.e., urology) would have been led to modify Streng's bladder diagnostic device to include an external closure on the filling lumen, based on the teachings in Budd relating to a heart mapping catheter. Accordingly, if it can be shown that a person skilled in the urology field would not have considered Budd to be relevant to any problem presented in the field of bladder diagnosis and treatment, and therefore would not have combined Budd with Streng in the asserted manner, then the rejections must be withdrawn as being improper.

Toward this end, Applicant submits herewith a Rule 132 Declaration from one of the inventors of the present application, Jonathan Mark Featherstone. As paragraphs 1-4 of the Declaration establish, Jonathan Mark Featherstone is a medical doctor in the United Kingdom, specializing in urology. Accordingly, it is submitted that Dr. Featherstone possesses at least ordinary skill in the art of urology, and particularly in the art of diagnostic tools for the human bladder, which is the art to which Streng applies. Therefore, his opinion with respect to how persons of ordinary skill in this particular art would view the cited references must be accorded all due weight and consideration.

As Dr. Featherstone declares, the invention is for treating bladder overactivity, typically causing urge incontinence, and requires the bladder to be distended by liquid to a volume at which electrical activity in the bladder wall is detected. This activity is indicative of detrusor

overactivity, and is mapped. Treatment of the site of activity is by ablation. Liquid, typically saline solution, is infused into the bladder through the urethra from a raised reservoir (e.g., a bag). When the bladder is distended, the reservoir may be lowered so that infusion (backfilling) ceases. Further lowering of the reservoir allows the bladder to void, or alternatively the reservoir may be disconnected to allow the patient to void naturally (Decl., ¶¶ 6 and 7).

In the invention it is important to hold the bladder at a fixed volume while the electrical activity is detected and treated. This ensures accuracy of treatment at the site of electrical activity, which in turn minimizes the necessity of a subsequent procedure. Such mapping of the bladder's electrical activity and treatment of the bladder take a considerable period of time to accomplish. Accordingly, the apparatus of the invention includes an external closure for the filling lumen that can be closed to maintain the bladder at the desired fixed volume for the period of time needed for mapping and treatment (Decl., ¶ 8).

Dr. Featherstone reviewed U.S. Patent No. 5,662,108 to Budd et al. as well as U.S. Patent No. 6,931,276 to Streng et al., and had the following remarks:

"Budd discloses a mapping device for a heart chamber. The heart is quite different from the bladder, being an organ that beats constantly and rapidly. In contrast a bladder is relatively passive – filling slowly and being voided infrequently. Budd has no means of holding the heart at a fixed volume, and to do so would cause a cardiac arrest. Budd does include a valve on the filling lumen of a balloon catheter, but this balloon does not control the volume of the pumping chamber of the heart (which is equivalent to the bladder in the invention) into which it is inserted. . . .

"Streng detects electrical activity in a human bladder as it is backfilled. Streng does not disclose mapping of the source of the activity. Although not stated in Streng, I would expect Streng to backfill the bladder using a reservoir raised above the patient on a stand – somewhat similar to that used to infuse saline or blood into a blood vessel." (Decl., ¶¶ 9-11.)

Responding to the Office Action's assertion that the invention is an obvious combination of the teachings of Budd and Streng, Dr. Featherstone respectfully disagreed, providing the

following observations as to how persons skilled in the urology field would view the cited references:

“There is no reason for Streng to maintain liquid in the bladder after an electrical (micturition) response is detected. Rather, once this response was detected, a medical practitioner using Streng’s apparatus would simply drop the reservoir down to allow bladder voiding. To maintain pressure (i.e., by closing an external closure on the filling lumen) would subject the patient to unnecessary discomfort to no purpose, and may have the effect of causing some unforeseen medical complication, such as a deterioration of bladder performance in patients who are already compromised. Furthermore, holding bladder pressure for a period using Streng’s device will achieve nothing that a transient increase in pressure cannot demonstrate by way of electrical response. It indeed could be considered to be medically unethical.

“Budd in my opinion would be unlikely to be considered by a person skilled in urology. Cardiac medicine is an entirely different specialty with a well-defined medical cohort distinct from that of urology. The two medical disciplines are entirely separate, both in staff and in hospital department.” (Decl., ¶¶ 13-14.)

It is respectfully submitted that Dr. Featherstone’s statements prove the falsity (or at least speculative nature) of the Office Action’s assertions at page 3 last line to page 4 line 8, namely, that it would have been obvious to use Budd’s external closure of his balloon catheter on Streng’s filling lumen “to provide for further testing of patients with urinary problems past the point of initially feeling the urge to void . . . , as healthy people can wait until an appropriate time and location to void, and not voiding immediately would provide further data for comparing and diagnosing patients with urinary problems. Additionally, an external closure for the filling lumen would provide for not having urine and the testing fluid unexpectedly/prematurely leave the bladder.”

In particular, Dr. Featherstone has indicated that to “maintain pressure (i.e., by closing an external closure on the filling lumen) would subject the patient to unnecessary discomfort to *no purpose*, and may have the effect of causing some unforeseen medical complication, such as a deterioration of bladder performance in patients who are already

compromised. Furthermore, holding bladder pressure for a period using Streng's device will achieve *nothing that a transient increase in pressure cannot demonstrate by way of electrical response*" (Decl., ¶13, emphasis added). That is, in Streng the objective is to trigger the micturition reflex, and once that has been accomplished, no purpose of Streng's would be served by maintaining the bladder completely full. The Office Action's speculative assertion to the contrary thus is erroneous from a medical standpoint, as Dr. Featherstone's Declaration makes clear.

Furthermore, and contrary to the Office Action, it is not even necessary to employ an external closure in order to prevent urine and testing fluid from unexpectedly or prematurely leaving the bladder. As long as the medical practitioner does not lower the filling reservoir to the point where the liquid begins to leave the bladder, there would not be any unexpected or premature voiding (see Decl., ¶ 7).

Finally, Dr. Featherstone has indicated his opinion that a person skilled in the art of urology would not consider Budd (concerned with the cardiac field) to be relevant to the field of bladder testing and treatment (Decl., ¶ 14). Indeed, as has already been explained, Budd's closure for his balloon catheter has an entirely different purpose from the closure of the apparatus defined by Claim 11 of the present application. There is no evidence of record that a person of ordinary skill in the bladder art would have been led to use Budd's balloon closure for a *completely different* reason in Streng's apparatus, where such a closure is not even necessary in order to accomplish Streng's purposes. On the contrary, Dr. Featherstone's Declaration establishes the opposite—that such a person would never even have considered Budd for the solution to any problem in the bladder art.

Thus, neither of the cited references alone discloses or suggests an apparatus having all of the limitations of Claim 11, and the references would not have been combined in the manner asserted in the Office Action. Therefore, Applicant respectfully submits that Claim 11 is patentable.

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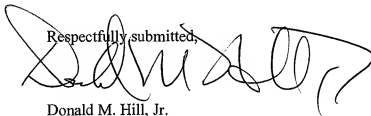
Claims 12-19 and 21-29 are patentable over the cited references for at least the reason that they incorporate all of the limitations of Claim 11. Furthermore, the cited references do not suggest the combination of the limitations of Claim 11 with the further features of each of Claims 12-19 and 21-29.

Conclusion

Based on the above remarks, it is submitted that all claims are patentable over the cited references and the application is in condition for allowance.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefor (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Donald M. Hill, Jr.', written over the typed name.

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